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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/621,316 | 07/18/2003 | Subhas C. Kundu | A4072.0044/P044 | 2537 |

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| EXAMINER | |
|---|---|
| VANIK, DAVID L | |
| ART UNIT | PAPER NUMBER |
| 1615 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/621,316 | KUNDU ET AL. | |
| | Examiner | Art Unit | |
| | David L. Vanik | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *17-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



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## DETAILED ACTION

Receipt is acknowledged of Applicant's response to the Election/Restriction requirement filed on 4/28/2005.

### *Election/Restrictions*

Applicant's election with traverse of Claims 1-16 in the reply filed on 4/28/2005 is acknowledged. The traversal is on the ground(s) that examining an antihistamine-based composition together with a method of using said composition to treat a mammal does not present the examiner with a search burden. This is not found persuasive because claims 1-16 (class 424, subclass 400+) and 17-21 (class 514, subclass 225.8) differ in scope as indicated by their distinct classification. As such, claims 17-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim.

It should also be noted that the Examiner withdraws the election of species requirement involving Claims 2 and 7. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/28/2005. The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 is drawn to an antihistamine-based composition comprising "0.85 citric acid." The way the claim is written, it is not clear if the "0.85" corresponds to moles, grams, milligrams, or milliliters of citric acid. As such, the claim is unclear and indefinite.

### *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,132,758 ('758).

'758 disclose antihistaminic syrups stabilized against degradation (abstract). The syrup compositions comprise well-known piperidine antihistamines, such as loratadine, descarboethoxyloratadine, and azatadine (column 2, lines 11-67). The compositions can also comprise a viscosity imparting agent, hydroxypropyl methylcellulose (Examples 4 and 5), a preservative, sodium benzoate (Examples 1, 3-9), water (Examples 1, 3-9), and buffer, citric acid (Examples 1, 3-9). The citric acid can be used to buffer the syrup to a pH of between 2-4 (column 1, lines 42-46). Many of the antihistamine-based compositions advanced by '758 also comprise aminopolycarboxylic acid in the form of EDTA (Examples 1, 3-7, 9). However, since the instant Claim 1 uses the open language "comprising" when describing the storage stable syrup composition,

other chemicals, such as aminopolycarboxylic acid, can be included in the composition. Moreover, as described by '758, it is not imperative that aminopolycarboxylic acid be present in the syrup (Example 8). Example 8, for instance, details the formulation of a storage stable antihistamine composition comprising azatadine, citric acid, glycerin, propylene glycol, water, sodium benzoate, and a flavoring agent without the addition of aminopolycarboxylic acid (Example 8).

According to '758, the syrup may also be essentially sugar free and may comprise sugar substitutes such as saccharin and sorbitol (Examples 4-5 and column 1, lines 15-20). Other therapeutic agents, such as analgesics, may also be included in the syrup (column 4, line 1-11 and Example 9). In terms of the degradation product tests, the compositions advanced by '758 degraded about 0.15% after 12 weeks of testing (column 5, lines 1-12). It is the examiner's position that the "about" 0.1% of degradation product after 12 weeks reads on the about 0.15% number obtained by '758.

The claims are therefore anticipated by US Patent 6,132,758 ('758).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 10-12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Application 2003/0026826 A1 ('826) in view of US 2002/0061340 A1 ('340) and further in view of 6,132,758 ('758).

'826 teach a sugar-free composition comprising an active agent, such as an antihistamine (paragraph 0082), a viscosity-imparting agent, such as hydroxypropyl methylcellulose (paragraphs 0077 and 0111), a preservative (paragraph 0086), and a sweetener, such as sodium saccharin or sorbitol (paragraph 0093). Other ingredients such as flavoring agents (paragraph 0120) and analgesics (paragraph 0082) may also be added to the composition.

'826 does not teach a composition comprising a buffer, such as citric acid, at a pH between 2-4.

'340 teaches a medical preparation which significantly inhibits microbial growth (abstract). In turn, this leads to increased preservation of the compositions (Table 1-4).

The compositions may be formulated to include antihistamines and other active agents (paragraph 0051). The compositions advanced by '340 may also include a number of viscosity-imparting and co-solvent agents (paragraphs 0011 and 0016). According to '340, the key to increased composition preservation is the addition of citric acid at a pH between 2.5 and 3.5 to a composition (paragraphs 0035 and 0037). Because the addition of citric acid at a pH between 2.5 –3.5 can advantageously modulate the degradation/preservation properties of an antihistamine-based composition, one of ordinary skill in the art would have been motivated to add citric acid to the composition proposed by '826. Based on the combined teachings of '826 and '340, there is a reasonable expectation that the addition of citric acid in an amount effective to buffer the composition to between a pH of 2.5 and 3.5 would effectively preserve an antihistamine-based composition, allowing it to remain stable for long periods of time. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add citric acid in an amount effective to buffer the composition of '826 to between a pH of 2.5 and 3.5 in view of the stable composition taught by '340.

'826 also does not teach a composition comprising loratadine, descarboethoxyloratadine, or azatadine.

The teachings of '758 are detailed above. '758 teach that loratadine, descarboethoxyloratadine, and azatadine are all effective antihistamines (column 2, lines 11-67). Because, as confirmed by '758, loratadine, descarboethoxyloratadine, and

azatadine are effective antihistimines, one of ordinary skill in the art would have been motivated to add loratadine, descarboethoxyloratadine, or azatadine to the composition proposed by '826. Based on the teachings of '758, there is a reasonable expectation that the addition of loratadine, descarboethoxyloratadine, or azatadine to the composition of '826 would result in an effective antihistamine-based composition. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add loratadine, descarboethoxyloratadine, or azatadine to the composition proposed by '826 in view of the teachings of '758.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over 6,132,758 ('758) in view of US Patent 5,658,919 ('919).

The teachings of '758 are detailed above. '758 does not teach the use of methylparaben, butylparaben or propylparaben as preservatives in a composition.

'919 teach an antihistamine-based cough syrup (column 4, lines 21-36). According to '919, methylparaben, butylparaben, propylparaben, and sodium benzoate are all effective preservatives for use in the syrup ((column 6, lines 1-15). Because, as confirmed by '919, methylparaben, butylparaben, and propylparaben are effective preservatives, one of ordinary skill in the art would have been motivated to add methylparaben, butylparaben, or propylparaben to the composition proposed by '758. Based on the teachings of '919, there is a reasonable expectation that the addition of

methylparaben, butylparaben, or propylparaben to the composition of '758 would result in an antihistamine-based composition with good preservation properties. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add methylparaben, butylparaben, or propylparaben to the composition proposed by '758 in view of the teachings of '919.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

5/18/05

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